

WOAH Reference Laboratory Reports Activities 2025

This report has been submitted: 23 septembre 2025 15:33

LABORATORY INFORMATION

*Name of disease (or topic) for which you are a designated WOAHO Reference Laboratory:	Koi herpesvirus disease
*Address of laboratory:	Friedrich-Loeffler Institute, Federal Research Institute for Animal Health
*Tel:	+493835171254
*E-mail address:	heike.schuetze@fli.de
Website:	
*Name (including Title) of Head of Laboratory (Responsible Official):	Dr. Heike Schütze (Head of NRL for IHN, VHS, ISA, EHN)
*Name (including Title and Position) of WOAHO Reference Expert:	Dr. Heike Schütze (WOAH RL for KHV-I)
*Which of the following defines your laboratory? Check all that apply:	Governmental

TOR1: DIAGNOSTIC METHODS

1. Did your laboratory perform diagnostic tests for the specified disease/topic for purposes such as disease diagnosis, screening of animals for export, surveillance, etc.? (Not for quality control, proficiency testing or staff training)

Yes

Diagnostic Test	Indicated in WOAHO Manual (Yes/No)	Total number of test performed last year	
		Nationally	Internationally
Indirect diagnostic tests			
ELISA	No	0	0
Direct diagnostic tests			
PCR (Engelsma et al. 2013)	Yes	4	0

TOR2: REFERENCE MATERIAL

2. Did your laboratory produce or supply imported standard reference reagents officially recognised by WOAHO?

No

3. Did your laboratory supply standard reference reagents (nonWOAH-approved) and/or other diagnostic reagents to WOAHO Members?

No

4. Did your laboratory produce vaccines?

Not applicable

5. Did your laboratory supply vaccines to WOAHO Members?

TOR3: NEW PROCEDURES

6. Did your laboratory develop new diagnostic methods for the designated pathogen or disease?

No

7. Did your laboratory validate diagnostic methods according to WOAHO Standards for the designated pathogen or disease?

- No
8. Did your laboratory develop new vaccines for the designated pathogen or disease?
9. Did your laboratory validate vaccines according to WOAHS Standards for the designated pathogen or disease?

TOR4: DIAGNOSTIC TESTING FACILITIES

10. Did your laboratory carry out diagnostic testing for other WOAHS Members?
- No
11. Did your laboratory provide expert advice in technical consultancies on the request of an WOAHS Member?

Yes

Name of the WOAHS Member Country receiving a technical consultancy	Purpose	How the advice was provided
THAILAND	Inquiry regarding primer-dimer issues in the Koi Herpesvirus qPCR assay (Gilad et al., 2004)	sending of detailed protocol for DNA extraction and qPCR including comments and notes for controls, reagents (kits), primer synthesis (purification, manufacturers)

TOR5: COLLABORATIVE SCIENTIFIC AND TECHNICAL STUDIES

12. Did your laboratory participate in international scientific studies in collaboration with WOAHS Members other than the own?
- No
13. In exercising your activities, have you identified any regulatory research needs* relevant for WOAHS?

Yes

Research need : 1

Please type the Research need: We have continued the research reported last year (see below). In this context, we have once again identified some KHV variants in Germany. Report 2024: Some KHV "variants" are not detected by qPCR according to Gilad et al 2004. Therefore, PCR according to Engelsma et al. (2013) followed by sequencing should always be used for monitoring and diagnosis of negative qPCR in animals suspected of having KHV-I. PS: Within the scope of the current EU Diagnostic Manual, CyHV-3 isolates of KHV-I to be controlled are defined as alloherpesviruses with $\geq 99\%$ identity to the viral DNA polymerase gene and/or the major capsid protein gene of CyHV-3 strains KHV/J, KHV/U and KHV/I (Aoki et al. 2007; Genbank accession numbers AP008984, DQ657948 and DQ177346).

Relevance for WOAHS Disease Control,

Relevance for the Code or Manual Manual,

Field Diagnostics,

Animal Category Aquatic,

Disease:

Infection with koi herpesvirus

Kind of disease (Zoonosis, Transboundary diseases)

If any, please specify relevance for Codes or Manual, chapter and title

(e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture)

Answer:

Notes:

Answer:

TOR6: EPIZOOLOGICAL DATA

14. Did your Laboratory collect epidemiological data relevant to international disease control?
- No
15. Did your laboratory disseminate epidemiological data that had been processed and analysed?
- No

16. What method of dissemination of information is most often used by your laboratory? (Indicate in the appropriate box the number by category and list the details in the box)

a) Articles published in peer-reviewed journals:

b) International conferences:

c) National conferences:

d) Other (Provide website address or link to appropriate information):

TOR7: SCIENTIFIC AND TECHNICAL TRAINING

17. Did your laboratory provide scientific and technical training to laboratory personnel from other WOA Members?

No

TOR8: QUALITY ASSURANCE

18. Does your laboratory have a Quality Management System?

Yes

Quality management system adopted	Certificate scan (PDF, JPG, PNG format)	
DIN EN ISO/IEC 17025:201	Akkreditierungsurkunde.pdf	Akkreditierungsurkunde.pdf

19. Is your quality management system accredited?

Yes

Test for which your laboratory is accredited	Accreditation body
(RT)-PCR, (RT)-qPCR, virus isolation, cell culture, immunofluorescence assay, ELISA, sequencing, genotyping etc	all fish diseases listed in the EU: KHV-I, IHN, VHS, ISA, EHN

20. Does your laboratory maintain a "biorisk management system" for the pathogen and the disease concerned?

Yes

The FLI has laboratory facilities ranging from S2/L2 to S4/L4. All previous work with KHV has been carried out under S2/L2 conditions.

TOR9: SCIENTIFIC MEETINGS

21. Did your laboratory organise scientific meetings related to the pathogen in question on behalf of WOA?

No

22. Did your laboratory participate in scientific meetings related to the pathogen in question on behalf of WOA?

No

TOR10: NETWORK WITH WOA REFERENCE LABORATORIES

23. Did your laboratory exchange information with other WOA Reference Laboratories designated for the same pathogen or disease?

Heike Schutze - - GERMANY

No
24. Are you a member of a network of WOA Reference Laboratories designated for the same pathogen?

No
25. Did you organise or participate in inter-laboratory proficiency tests with WOA Reference Laboratories designated for the same pathogen during the past 2 years?

Yes

Purpose of the proficiency test:	Role of your Reference Laboratory (organiser/ participant)	No. participating Laboratories	Participating WOA Ref. Labs/ organising WOA Ref Lab
validation of qPCR (Gilad et al. 2004) with TaqMan Universal PCR Master Mix (Applied Biosystems)	participant	FLI independently PCR analyses by three colleagues	yes

26. Did your laboratory collaborate with other WOA Reference Laboratories for the same disease on scientific research projects for the diagnosis or control of the pathogen of interest?

No

TOR11: OTHER INTERLABORATORY PROFICIENCY TESTING

27. Did your laboratory organise or participate in inter-laboratory proficiency tests with laboratories other than WOA Reference Laboratories for the same pathogen during the past 2 years?

Yes

Purpose for inter-laboratory test comparisons ¹	Role of your reference laboratory (organizer/participant)	No. participating laboratories	Name of the test	WOAH Member Countries
Identification of IHNV, VHSV, SVCV, IPNV, KHV, ISAV	organizer	21	National Inter-laboratory comparison (FLI-RT_2024 and FLI-LV_2025)	GERMANY,
Identification of IHNV, VHSV, EHN, SVCV, IPNV, KHV, ISAV, SAV	participant	44	EURL Inter-Laboratory Proficiency Test 2024	GERMANY,

TOR12: EXPERT CONSULTANTS

28. Did your laboratory place expert consultants at the disposal of WOA?

Yes

Kind of consultancy	Location	Subject (facultative)
reviewing the draft Aquatic Manual introductory Chapter 1.1.2 'Validation of diagnostic assays for infectious diseases of aquatic animals'	WOAH Website/ E-Mail	review
Survey on Aquatic Animal Health Research Priorities	online	survey
Survey: key user consultation on situation reports developed by WOA on aquatic animal diseases	online	survey
Contributing to the development of a WOA app for KHV-I, including providing representative images.	E-Mail	contributing
Participation in the workshop to identify the highest-priority research areas for finfish diseases	WOAH HQ Paris	participant

29. Additional comments regarding your report:

Yes

involvement in WOA documents at the national level